A MULTI-CENTER, PROSPECTIVE CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFECTIVENESS OF THE CT LUCIA 611P POSTERIOR CHAMBER INTRAOCULAR LENS FOR CORRECTION OF APHAKIA FOLLOWING CATARACT REMOVAL (IDE 611 STUDY)

PROTOCOL # CT LUCIA 611P ONT-301-17, VERSION E

STUDY SYNOPSIS

1. Study Objective

To establish the safety and effectiveness of the CT LUCIA 611P posterior chamber intraocular lens (IOL) for the correction of aphakia following extracapsular cataract extraction via phacoemulsification in adult patients.

2. Study Device

The CT LUCIA 611P is a posterior chamber hydrophobic acrylic IOL, which is designed for implantation in the capsular bag following cataract extraction, contained in a BLUEJECT injector. The IOL is a single-piece design with 6.0 mm optic diameter and 13.0 mm overall diameter. The optic of the CT LUCIA 611P is monofocal biconvex aspheric in design, with edges designed to minimize mass; the lens haptics are modified C-loop with 0° angulation.

3. Study Endpoints

- Effectiveness: The primary effectiveness endpoint is the proportion of subject [redacted]
- Safety: The primary safety endpoints are the incidence of adverse events (AE).

4. Study Design

This is a prospective, multi-center single-arm clinical study. Subjects will be enrolled at approximately 15 investigational sites located in the U.S. Only 1 eye per subject may receive the study device. All subjects who undergo surgery and study device implantation will be followed for 12 months post-surgery.

5. Subject Population

Adult subjects undergoing extracapsular cataract extraction via phacoemulsification followed by implantation of a posterior chamber IOL.

6. Number of Eyes

390 eyes enrolled, with ≥ 300 eyes followed through 12 months postoperatively.

7. Study Treatment

Candidate patients will be screened to determine study eligibility, then examined to obtain their medical and ophthalmic history and establish baseline ocular condition. Qualified subjects will undergo extracapsular cataract extraction via phacoemulsification followed by implantation with the CT LUCIA 611P IOL in the study eye. Postoperatively, subjects will undergo protocol-specified ophthalmic examinations at regularly scheduled intervals.

8. Examination Schedule

Scheduled examinations will be performed at the intervals shown below:

- Pre-operative Visit (-90 - 0 days)
- Operative Visit (Day 0)
- 1 Day Postoperative Visit (1 - 2 days post-surgery)
- 1 Week Postoperative Visit (7 - 14 days post-surgery)
- 1 Month Postoperative Visit (30 - 60 days post-surgery)
- 6 Months Postoperative Visit (120 - 180 days post-surgery)
- 12 Months Postoperative Visit (330 - 420 days post-surgery)

Note: Unscheduled visits may occur at any time during the study participation period.

9. Clinical Assessments/Procedures

The following clinical assessments will be performed at scheduled examination visits as shown in **APPENDIX 1: SCHEDULE OF CLINICAL ASSESSMENTS/PROCEDURES**:

- Medical and ophthalmic history
- Concomitant medication use
- Study eye axial length (AL), anterior chamber depth (ACD) and keratometry (K) measurement
- Study eye cataract removal and IOL implantation information
- Uncorrected and best-corrected distance VA
- Manifest refraction (MR)
- Slit lamp examination (SLE)
- Dilated fundus examination (DFE)
- Intraocular pressure (IOP) measurement
- Adverse event (AE) determination

Note: Clinical assessments/procedures performed at unscheduled examination visits will be determined at the study investigator's discretion.

10. Study Duration

The duration of each subject's study participation is nominally estimated to be approximately 13 months; however, duration of participation is affected by the time lapse between the Preoperative Visit, which may occur between Day -90 and Day 0, and the Operative Visit on Day 0. Each subject will be followed for 12 months after the Operative Visit. *Of note, the 12-Month Visit may occur at any time between 11 and 14 months postoperatively.*

The total anticipated duration of this clinical investigation is approximately 21 – 26 months.